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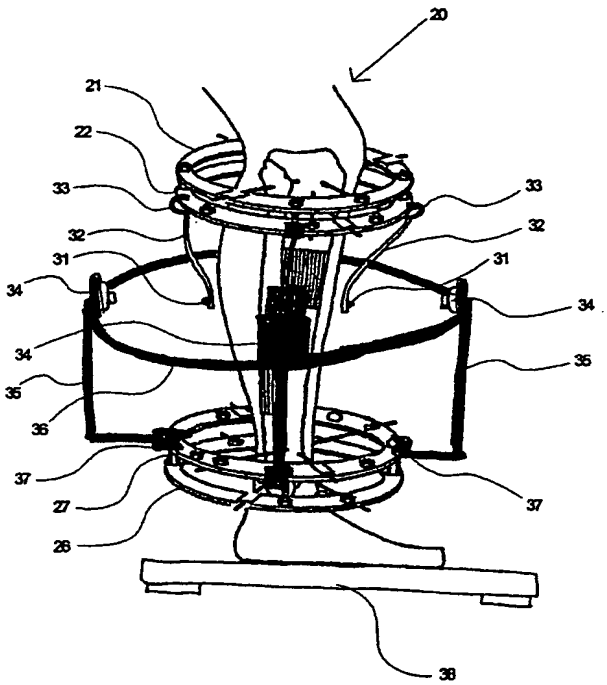
(54) Title: METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE



(57) Abstract: Method and apparatus for measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations. The external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, the bone is subjected to strain, and corresponding measurements and/or detections are made of the relative displacement by contactless and/or

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METHOD OF MEASURING BONE STRENGTH, APPARATUS FOR MEASURING BONE STRENGTH AND FIXATION DEVICE

Field of the invention

The invention relates to a method of measuring the strength or stiffness of a bone, an apparatus for measuring the strength or stiffness of a bone and an external fixator for supporting a bone.

Background of the invention

When a bone, for example a bone in a limb of an animal or a human being, is healing after a fracture, it is known to support such a bone with an external holding device called a fixation device or a fixator. Such a fixator serves to fixate the ends of the bone in relation to each other as well as to carry the load or part of the load which a patient may have to place on the bone during the healing process.

Further, it is known to use such a fixator when extending the length of a bone. This is done by performing an osteotomy, i.e. by performing a substantially transversal cut in the bone, by preferably gradually pulling the ends of the bone apart at a predetermined and limited distance and by fixating the ends of the bone adjacently to each other. Hereby, the space between the ends of the bone will gradually be filled with new bone material, after which the ends of the bone may be pulled apart once again in order to increase the length of the bone even further. Eventually, when the bone has reached the required length and developed the necessary strength and stiffness, the external fixating device, the fixator, which may be unilateral, semicircular or circular, may be removed.

In order to determine the right time for removal of the fixator during a healing process and/or during a revalidation process, it is known to evaluate the consolidation of the fracture or the osteotomy by using radiography, e.g. x-ray-technology, DEXA (dual or double energy x-ray absorption), CT-scanning, or other similar methods

such as ultrasound, other scanning methods etc. However, these methods rely on the assessment skills and experience of the person or persons, e.g. the physician or the surgeon, using the method. Thus, an accurate and objective determination can not be made by using this method. Further, it is known to perform a purely physical examination in order to determine the strength or stiffness of a healing bone, e.g. by having the physician grab the limb and physically try to flex, bend and/or twist the limb in order to assess the state of healing. Of course, this is based solely on the assessment skills and experience of the person or persons, e.g. the physician, carrying out the examination.

In this context, it is understood that the terms stiffness and strength of a bone will refer to the same physical parameter of a bone, e.g. the resistance to deformation once a force or load is placed on the bone.

Further, it is known to detect or measure the deformation of a part using a fixator, when a load is placed on the assembly of the bone and the fixator.

An example of this is described in US 5,792,076, which relates to a fixation device having an elongated optical fiber. The fixation device is affixed to a patient's bone by pins attached to a fixation bar. The fixation bar comprises the elongated optical fiber and light is transmitted through the optical fiber to an exit point where the intensity is measured. As the bone fracture is gradually healing, the load, e.g. the weight or part of the weight of the patient, will gradually be transferred from the fixation bar to the bone of the patient, giving rise to a change in the intensity of the transmitted light. Thus, a physician will be able to assess when the fracture has fully healed by observing the change in the light intensity.

This method, however, suffers from the disadvantage that the fixation bar is an integral part of the system of which the strength is evaluated. Thus, the result of the assessments will not necessarily provide a true picture of the strength of the bone. Further, the assessment is given of a deformation of the fixation bar which is mounted unilaterally. Thus, the deformation of the bone in other dimensions will not

be evaluated by this method. Further, in many cases, a fractured bone will have one or more neighboring bones, for example in a lower arm or in a lower leg, which means that when a limb is subjected to a certain load or a strain, this load or strain will be dissipated on the bones in the limb and possibly also on any fixation devices used. Thus, the load, force or strain placed on the fractured bone will be difficult to determine on the basis of the load placed on the limb, and the deformation of the bone and the limb will depend on the assembly as a whole. Thus, for example, a load on a limb in an axial direction may of course result in an axial deformation of the fracture bone, but it may also result in an angular deformation, e.g. a twisting motion, and a bending deformation.

It is also known to use means for measuring or detecting the strain and/or deformation of the bone, wherein said means is attached to the bone or the limb.

An example of such a method is described in EP 0 324 279 A1, wherein the bending of e.g. a lower leg having a healing fracture is measured by means of a goniometer. Bone pins are placed on each side of the fracture site, and a goniometer is attached to these pins and positioned substantially parallelly with the axis of the bone. The deformation, i.e. the bending of the bone, is measured while simultaneously applying force to the bone of the patient. This force, which may be constituted by the weight of the limb, e.g. the lower leg, may be measured by a scale placed under one end of the limb, e.g. under the heel of the patient.

Another example of such a system is described in US 5,339,533.

Both systems also suffer from the disadvantages described above with the exception of the fixation bar which is not applied in these systems when determining the strength of the bone. However, by using these systems, only the bending deformation of the bone will be determined. Thus, the true strength of the bone will not be evaluated.

A further prior art fixation device is described in WO 98/00062. This fixation device has two ring-shaped members attached to a fractured bone by pins on each side of the fracture. The two ring-shaped members are connected to each other by connecting studs in order to support the bone. One of the ring members comprises a first and a second element which may be rotated in relation to each other. The first element carries the connecting studs while the second element is connected to the pins. The two elements may be rotated in relation to each other when a force is exerted on the bone, i.e. the healing fracture, via one of the elements whereby the two bone parts will be subject to a torque attempting to twist the two bone parts in relation to each other. The extent of the movement, e.g. the angle, and the exerted force corresponding to the torque, may be measured in order to obtain values reflecting the strength of the bone.

By this system, only the torsional strength of the bone, e.g. the healing bone, may be determined which may not provide a true picture of the strength of the healing bone, e.g. the state of healing, as the resistance to axial deformation and bending deformation will not be detected and these resistances may not be proportional to the resistance of a torsional force. Thus, the true state of the healing process and the true strength of the bone, e.g. the healing bone fracture, may not be determined by this method.

The prior art methods and systems for determining the strength or stiffness of a healing bone generally suffer from the drawback that the strength of the healing bone will not be determined with the required accuracy. Thus, the optimal time for removal of a fixation device cannot be determined by using these methods and systems.

When trying to decide when a healing bone, e.g. a bone healing after a fracture or after an ostetomy performed in order to increase, reduce or alter the angling of the bone, has gained sufficient strength to allow a fixation device, e.g. an external fixation device to be loosened or removed, it is important to find the optimal or nearly optimal time for loosening or removal.

If the fixation device is removed too soon, the healing bone may be refractured, whereby the patient will suffer additional discomfort and possibly complications in the healing process. Hereby, the healing period will be extended and the health service as well as society in general will have to spend unnecessary resources, e.g. loss of work, occupation of hospital resources etc., and the patient will suffer from additional discomfort and loss of income.

Therefore, there has been a tendency to extend the period of which a fixation device is used until it is safe to assume that a refracture will not occur. This tendency is enhanced by the fact that existing methods of determining the state of a healing bone involve some inaccuracies. Consequently, in most cases, the fixation device is left on the patient for a longer period of time than is necessary in order to ensure that a refracture will not occur.

As the healing process has proven to be accelerated when the fracture is subjected to normal or near-normal load situations as soon as it is deemed safe, the healing process as a whole is reduced. However, as there is a tendency to maintain the healing bone supported by the fixator longer than strictly necessary in order to be on the safe side, this will extend the healing and revalidation time leading to unnecessary resource spending, loss of work, unnecessary occupation of hospital and medical resources, loss of income, prolonged discomfort of the patient etc.

Thus, it is an object of the invention to provide an improved method of determining the strength or stiffness of a bone, and in particular a healing bone. A further object of the invention is to provide a method of determining the strength of a bone, and in particular a healing bone, whereby the strength of the bone may be determined with improved accuracy, whereby an improved method of determining the time for removal of a holding device, and in particular an external holding device, may be provided.

Another object of the invention is to provide an improved apparatus for determining the strength or stiffness of a bone, and in particular a healing bone. A still further object of the invention is to provide an apparatus for determining the strength or stiffness of a bone, and in particular a healing bone, whereby the strength or stiffness of the bone may be determined with improved accuracy, whereby an improved method of determining the time for removal of a holding device, and in particular an external holding device, may be provided.

It is also an object of the invention to provide a fixation device for a healing bone, whereby the fixation device will facilitate improved determination of the strength or stiffness of the bone, e.g. the healing bone.

It is a further object of the invention to provide means for reducing the time during which a patient will have to be equipped with an external fixator, whereby costs involved with healing bones, e.g. bones healing after a fracture or after an osteotomy, will be reduced.

These and other objects are achieved by the invention.

Summary of the invention

As stated in claim 1, the invention relates to a method of measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy which has been performed in order to extend, reduce or alter the angle of the bone, whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subject to strain, and whereby corresponding measurements and/or detections are made of the relative displacement by contactless measurement of and/or detection means.

Hereby, a measurement is made which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and also allow measurements to be performed in more than one dimension.

Preferably, as stated in claim 2, measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

As stated in claim 3, the external fastening means may be part of external fixing means for supporting the bone. Hereby, a flexible and convenient way of obtaining measurements is achieved which are necessary for evaluating the healing state of a bone as fastening means already attached onto the patient may be used when performing the method.

As stated in claim 4, the bone is subjected to strain, preferably by the patient, and the strain is measured, detected and/or visualized. Hereby, deformations may be induced in a convenient manner and the cause of the deformations be documented.

As stated in claim 5, the corresponding measurements and/or detections of the relative displacement and strain on the bone may be correlated and/or recorded, whereby a comparison of the deformations and the causes may be made, whereby an assessment of the strength of the bone may be conveniently performed.

The invention also concerns a method, as stated in claim 6, which relates to the measurement of the strength of a bone, in particular a bone healing after a fracture or after an osteotomy, whereby external fastening means are attached onto the bone in

at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement in at least two dimensions of the strain on the bone.

Hereby, a method is achieved which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will allow measurements to be performed in more than one dimension providing improved measurements of the induced deformations that those of prior art methods.

Preferably, as stated in claim 7, the measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone.

As stated in claim 8, the external fastening means may be part of external fixing means for supporting the bone. Hereby, a flexible and convenient way of obtaining the measurements necessary for evaluating the healing state of a bone is achieved as fastening means already attached onto the patient may be used when applying the method.

As stated in claim 9, the bone may be subjected to strain by the patient and the strain may be measured, detected and/or visualized. Hereby, deformations may be induced in a convenient manner and the cause of the deformations be documented.

As stated in claim 10, the corresponding measurements and/or detections of the relative displacement and the strain on the bone may be correlated and/or recorded, whereby a comparison of the deformations and the causes may be made, whereby an assessment of the strength of the bone may be conveniently performed.

Further, the invention relates to an apparatus, as claimed in claim 11, for measurement of the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement by contactless measurement and/or detection means between said at least two external fastening means.

Hereby, an apparatus is provided whereby a measurement is made which will provide a more accurate assessment of the strength and/or stiffness of a bone as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and allow measurements to be performed in more than one dimension by the apparatus.

Preferably, as stated in claim 12, the apparatus is provided with means for measurement and/or detection of induced strain on the bone. Hereby, the cause of the deformations may be readily documented and utilized in connection with the assessment of the bone strength.

As stated in claim 13, the apparatus may be provided with means for correlating said measurements and/or detections of relative displacement and strain, whereby a comparison of the deformations and the causes may be made by the apparatus, whereby an assessment of the strength of the bone may be conveniently performed on the basis hereof.

As stated in claim 14, the means for contactless measurement and/or detection of relative displacement between said at least two external fastening means may facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measure-

ments may be made of any deformations induced by any given force or load placed on the bone.

As stated in claim 15, the external fastening means may be part of external fixing means for supporting the bone. Hereby, an apparatus according to this embodiment may be utilized in a flexible and convenient way to obtain the measurements necessary for assessing the healing state of a bone as fastening means already attached onto the patient may be used in connection with or as part of the apparatus.

As stated in claim 16, the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring force to/from the limb to/from measuring means. Hereby, the patient may exert the load or force necessary to induce the deformations of the bone or bones. The weight of a limb alone may constitute a load or the patient may place more or less bodyweight on the limb. When one end of the limb is positioned, preferably by a bracket or similar means, the patient may exert force on the bone in any other direction than the vertical direction, e.g. horizontal direction, attempting to twist the bone etc., whereby more varied deformations may be induced.

As stated in claim 17, the apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected strain. Hereby, the cause of the deformations may be documented by the apparatus, whereby an assessment of the strength of the bone may be performed by a skilled user.

As stated in claim 18, the apparatus may preferably comprise means for indicating, visualizing and/or recording the measured and/or detected relative displacement, whereby the result of the measurements may be used for immediate or subsequent assessments.

The invention further relates to an apparatus, as claimed in claim 19, for measurement of the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, said apparatus comprising external fastening means for con-

nection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means, and said apparatus being provided with means for measurement and/or detection of an induced strain on the bone.

Hereby, an apparatus is provided by means of which a more accurate assessment of the strength and/or stiffness of a bone may be performed as the measuring arrangements of the apparatus will facilitate measurements in more than one dimension and thus provide improved measurements of the induced deformations than those of prior art apparatuses.

Preferably, as stated in claim 20, the apparatus may be provided with means for correlating said measurements and/or detections of relative displacement and strain, whereby a comparison of the deformations and the causes may be provided by the apparatus, whereby an assessment of the strength of the bone may be conveniently performed by a skilled person, e.g. a physician.

Preferably, as stated in claim 21, the means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means may facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement. Hereby, measurements may be made of any deformations induced by any given force or load placed on the bone. The means for detection and/or measurement of relative displacement in at least two dimensions may be configured as mechanical measuring means, e.g. slide gauges or other similar means connected to the two external fastening means in such a manner that measurements may be made in two or more dimensions.

A stated in claim 22, the external fastening means may be part of external fixing means for supporting the bone. Hereby, an apparatus according to this embodiment may be utilized in a flexible and convenient way to obtain the measurements neces-

sary for assessing the healing state of a bone as fastening means already attached onto the patient may be used in connection with or as part of the apparatus.

As stated in claim 23, the apparatus may be provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring force to/from the limb to/from measuring means. Hereby, the patient may exert the load or force necessary to induce the deformations of the bone or bones. The weight of a limb may constitute a load alone or the patient may place more or less bodyweight on the limb. When one end of the limb is positioned, preferably by a bracket or similar means, the patient may exert a force on the bone in any other direction than the vertical direction, e.g. horizontal direction, attempting to twist the bone etc., whereby more varied deformations may be induced.

As stated in claim 24, the apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected strain. Hereby, the cause of the deformations may be documented by the apparatus, whereby an assessment of the strength of the bone may be performed by a skilled user.

As stated in claim 25, the apparatus may comprise means for indicating, visualizing and/or recording the measured and/or detected relative displacement, whereby the result of the measurements may be used for immediate or subsequent assessments.

Finally, the invention also pertains to an external fixation device, as stated in claim 26, which relates to an external fixator for supporting a bone, e.g. a bone in a limb of an animal or a human being, said fixator comprising means for fastening onto the bone in at least two locations and connecting means for providing a preferably adjustable connection between said fastening means, wherein said connection means are replaceable and wherein measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable to said at least two external fastening means.

Hereby, a fixator for supporting a bone or bones is provided which may also serve as fastening means when performing measurements of the flexibility of the bone. Thus, the measurements and hence the assessment of the healing state of the bone may be performed in a expedient manner when a fixator according to the invention is utilized.

Preferably, as stated in claim 27, said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are contactless. Hereby, a measurement may be made which will provide a more accurate assessment of the strength and/or stiffness of a bone, as the measuring arrangements will not have any influence on the result of the measurements, e.g. the measuring arrangements will not contribute to the stiffness of the structure, i.e. the bone or bones subject to the measurements. Further, the contactless measuring arrangement will allow increased flexibility when setting up the arrangement and also allow measurements to be performed in more than one dimension.

As stated in claim 28, said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means may be configured for detection and/or measurement of relative displacement in at least two dimensions. Hereby, a more accurate assessment of the strength and/or stiffness of a bone may be performed as the measuring arrangements will allow measurements to be performed in more than one dimension and provide better measurements of the induced deformations than those of prior art systems. The means for detection and/or measurement of relative displacement in at least two dimensions may be configured as mechanical measuring means, e.g. slide gauges or other similar means connected to the two external fastening means in such a manner that measurements may be made in two or more dimensions. Other measuring means than purely mechanical ones may be used as well.

As stated in claim 29, said at least two external fastening means may each comprise or be connected to a structural member which surrounds the body part containing the bone at least partly, said preferably adjustable connection between said fastening

means being connected to said structural members. Hereby, the fastening means may constitute a firm connection for attachment of the measurement and/or detection means.

As stated in claim 30, said structural members may comprise separate and/or relatively movable parts which may be joined and/or adjusted in order to surround a limb at least partly. Hereby, the structural members may be used flexibly as they may be adjusted in relation to the actual use as the structural members may be easily attached and removed.

As stated in claim 31, the connection means comprises one, two, three, four or more connecting rods which may preferably be adjustably placed between said at least two fastening means. Hereby, a versatile fixator is achieved which may be used in a wide number of applications.

As stated in claim 32, the measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable to said structural members forming part of or being connected to said at least two external fastening means. Hereby, the fastening means may conveniently be fastened onto appropriate places, e.g. the front of the bone, the side etc., and provide a firm connection.

As stated in claim 33, the measurement and/or detection means for detection and/or measurement of relative displacement may be connected to the at least two external fastening means and/or said corresponding structural members by means which also serve as fixation means for said preferably adjustable connection between said fastening means. Hereby, the fastening of the measurement and/or detection means may be performed in a surprisingly simple manner and by means of a minimum of technical means.

As stated in claim 34, the measurement and/or detection means for detection and/or measurement of relative displacement may comprise electrical, magnetic or electro-

magnetic measurement and/or detection means. Hereby, the fixator may be flexibly used in connection with a number of different measuring arrangements selected according to actual use, actual measurement, and/or processing arrangements and/or other preferences.

As stated in claim 35, the measurement and/or detection means for detection and/or measurement of relative displacement may comprise optical measurement and/or detection means, for example in the form of digital video cameras or light emitting devices such as for example LEDs. Hereby, an advantageous measuring arrangement is achieved which is relatively easy to install and use and which facilitates effortless use also by person without any particular technical skills.

As stated in claim 36, the measurement and/or detection means for detection and/or measurement of relative displacement may comprise one or more measurement and/or detection means.

As stated in claim 37, the measurement and/or detection means for detection and/or measurement of relative displacement in at least two dimensions comprise two or more measurement and/or detection means placed at a circumferential distance, e.g. in relation to an axis of the bone, whereby the accuracy of the measurements may be enhanced and hence also the accuracy of the assessment of the strength of the bone and consequently the healing state of the bone.

The figures

The invention will be described below with reference to the drawings of which

fig. 1 illustrates a bone separated in two parts and deformations of this bone schematically,

fig. 2 shows a fixation device attached onto the lower leg of a human being,

fig. 3 illustrates the fixation device shown in fig. 3 with deformation measuring means attached,

fig. 4 shows an alternative deformation measuring arrangement, and

fig. 5 shows a block diagram illustrating the signal processing according to a further embodiment of the invention.

Detailed description

Fig. 1 illustrates a bone 10, for example a bone of a human being. This bone 10 has been separated in two parts 10a and 10b, for example a proximal part 10a and a distal part 10b. The separation may be due to a fracture or to an osteotomy operation. During healing, the bone will flex at the place of separation when exposed to stress. The flexing may be illustrated by the two bone part vectors 11a and 11b, extending from an origin 12a and 12b, respectively. The direction of these vectors represents axes of the bone parts 10a and 10b, e.g. local bone axes and not necessarily an axis of the bone 10.

Obviously, the bone parts 10a and 10b will move longitudinally when exposed to stress. For example, the bone parts will move towards each other when subjected to an at least partly longitudinal force, whereby the healing part of the bone will be compressed. This will be indicated by a reduction of the distance 13 between the origins 12a and 12b of the bone part vectors 11a and 11b, respectively.

Further, application of force and/or momentum to the bone 10 may induce a relative rotational movement of the two bone parts 10a and 10b, which is illustrated by a vector 14a and a vector 14b, extending from the origins 11a and 11b, respectively. These vectors 14a and 14b may extend at right angles from the bone part vectors 11a and 11b, respectively, and/or they may extend in one and the same direction, preferably in a direction perpendicular to one or both of the bone part vectors 11a and 11b.

In an unstrained situation, these vectors extend in a reference direction, illustrated by the punctuated lines 15a and 15b, respectively. As one or both of the bone parts may be rotated when strained, angles 16a and 16b between the vector 14a and the refer-

ence direction 15a and between the vector 14b and the reference direction 15b respectively, serve to indicate the rotational movement of the bone parts 10a and 10b and hence also the relative rotational displacement of the bone parts.

Finally, application of force and/or momentum to the bone 10 may induce an angular displacement of the bone parts 10a and 10b and hence the bone part vectors 11a and 11b, causing a change of direction of the bone part vectors. These angles may be indicated by the angle of the bone part vectors in relation to a reference direction, or by the angle of the vectors 14a and 14b, respectively, in relation to a reference direction (not shown) in a plane defined by the bone part vector 11a and the vector 14a and/or the bone part vector 11b and the vector 14b. As will be explained later, the latter of these two methods will be preferable in connection with the invention.

When determining the strength or stiffness of a bone, and in particular a healing bone, it is desirable to be able to determine all the above-defined relative movements, e.g. the change in distance 13, the change in difference between the angles 16a and 16b and the relative change of direction of the bone part vectors 11a and 11b when forces and/or torques may be exerted on a bone, an assembly of bones and/or a limb.

The invention will now be explained further by reference to an external holder or fixator as illustrated in fig. 2. This holder may be used to support a fractured bone while healing or, as illustrated, for a leg 20 on which an osteotomy is performed in order to extend, reduce or alter the angle of the bone, and to support the bones during the healing process. The external fixator may be unilateral, e.g. support by only one axial supporting bar or rod, semicircular, e.g. support of half a circle surrounding the bone, or circular, e.g. support is essentially circumferentially.

In fig. 2, the use of the external fixator is illustrated in connection with the lower leg of a human being, but the fixator may obviously also be used in connection with other limbs and/or bones if appropriately modified. Further, an external fixator may be used in connection with animals as well as human beings.

The fixator comprises a number of ring-shaped structural members 21, 22, 26 and 27. The upper ring-shaped member is attached onto one or both bones, the tibia 29 and the fibula 28, of the lower leg by bone pins, bone screws, bone rods or as shown by bone wires 23 connected to the ring-shaped member 21 by connectors 24 and 25. The connectors 24 and 25 allow the bone wire to be fastened onto the ring-shaped member 23 with sufficient tensile strength to assure a rigid connection between the ring-shaped member 21 and the bone or bones 29 and 28.

The ring-shaped member 22 is similarly connected to one or both of the bones 28 and 29 by wires 23 and connectors 24 and 25. The lower ring-shaped members 26 and 27 are fastened onto the lower part of one or both of the bones 29 and 28 in the same fashion.

The upper ring-shaped members 21 and 22 are located above the healing sites 29a and 28a of the tibia 29 and the fibula 28, respectively, and the lower ring-shaped members are located below the healing sites 29a and 28a. Connecting means 30 in the form of connecting rods are placed between the ring-shaped members in order to support the bones, i.e. the leg. The connecting rods are threaded, at least at the ends, whereby they can be connected to the ring-shaped members by nuts. Longer connecting rods 30a are located between the ring-shaped members 22 and 27 and shorter connecting rods 30b are located between the ring-shaped members 21 and 22 and the ring-shaped members 26 and 27.

As the connecting rods are threaded, the distance between the ring-shaped members can be adjusted. The distance between the ring-shaped members 21 and 22 and the ring-shaped members 26 and 27, respectively, can be adjusted in dependency of the actual placing of the corresponding bone wires 23. The distance between ring-shaped members 22 and 27 can be adjusted by the connecting rods 30a in order to fixate the bone parts appropriately in relation to each other.

When the fixator is used in connection with a leg with a (simple) fracture, the fixator can be adjusted to achieve the natural relations between the bone parts, after which the relationship is maintained until the fracture site has healed sufficiently.

When the fixator is used in connection with a more complex fracture or in connection with a bone extension/reduction/re-angling, the connecting rods 30a are initially adjusted to define an appropriate distance between the bone ends, i.e. the fractured bone ends or the separated bone ends, whereby a healing process, e.g. a bone mass producing process, will begin. Once the healing has started, i.e. the production of bone mass, and has reached a certain stage, the connecting rods 30a can be adjusted to pull the bone ends further apart, whereby the healing process will proceed and produce bone mass in the now intermediate space between the bone parts. This may be repeated until the desired length of the bone or bones has been achieved. A consolidation of the healing site will then have to take place, after which the fixator may be loosened and/or eventually permanently removed.

The stage of the healing process, e.g. the stiffness or strength of the healing fracture site, can be determined as shown in fig. 3. This figure corresponds to fig. 2. However, the connecting rods 30a of the fixating device have been loosened (in the early stages of the healing process) or removed, leaving the leg and the bones 29 and 28 unsupported or partially unsupported. A number of light emitting devices such as for example light emitting diodes (LEDs) 31 has been placed on one of the upper ring-shaped members 22. These LEDs are each mounted at one end of a fixture 32, which has attachment means 33 at the other end by which it is connected to the ring-shaped member 22, for example by through-holes in the ring-shaped member.

Correspondingly, a bracket has been mounted on one of the lower ring-shaped members 27. The bracket comprises a number of rods 35 which are attached by clamping means 37 to the ring-shaped member 27 at the lower ends, for example by bolt and nut. At the upper end of the rods 35, a ring-shaped support has been mounted, and a number of mini-cameras 34 have been placed on the support 35 and/or the rods 35. The cameras, which may be digital video cameras such as USB-cameras, are placed

in such a manner that they are located in the proximity of the light emitting devices 31.

When a load, a force and/or a torque is exerted upon the leg 20, the bones will be able to flex freely, as the connecting rods have been removed. This flexing will be transferred to corresponding movements of the ring-shaped members 21 and 27 and hence also the light emitting devices 31 and the cameras 34. By reference to fig. 1 and the corresponding explanation, it is evident that the relative movements of the light emitting devices 31 and the cameras 34 will provide a full and complete picture of the flexing of the bones in all possible dimensions, and when correlated with the load or force placed onto the bone or bones also on the strength of the healing structure, as will be explained at a later point.

For example, an axial deformation will be determined by a vertical change of the position of the image of the light-emitting device 31 on the corresponding camera 34. A rotational flexing will be determined by a horizontal change of the position of the image of the light-emitting device 31 on the corresponding camera 34, and as more than one LED/camera arrangement is used, in the example four, a bend, e.g. an angular flexing of the bone, will be detected by a difference in the changes of the positions of the image of the light-emitting device 31 on the corresponding camera 34. It is evident that more than two camera/LED-arrangements of this particular configuration placed at different locations may be necessary to achieve this. However, only one camera/light emitting arrangement will suffice to provide a measurement of the deformations in two or more dimensions as will be described at a later point. Processing of the signals or results from the cameras 34 is necessary in order to obtain results indicating the actual one, two or three-dimensional flexing movements/deformations. Such processing methods are known to persons skilled in the art and will not be described in detail.

Figure 3 shows that four camera/LED-arrangements may be used and evenly distributed on the circular ring-shaped support 36, e.g. with an angle interval of 90°. Other

configurations obvious to a skilled person may be used as well, and additional camera/LED-arrangements may be used, e.g. two, three, four, five etc.

Further, it is obvious that the LED-arrangements 32, 33, 34 and the camera arrangements 34, 35, 36, 37 may be configured as units which may be attached onto the corresponding ring-shaped members 22 and 27 as units whereby the placing of the measuring arrangements may be performed in an easy and fast manner.

Fig. 3 illustrates the foot of the patient being placed on a force plate 38 in order to determine the load or force, which is exerted on the leg/bone/bones. This force plate 38 may be constituted by a simple weight, a weight cell or other suitable means. Further arrangements may be configured to measure or determine other forces than substantially vertical forces, e.g. horizontal forces, or torques exerted on the leg. These arrangements may comprise a bracket or similar means (not illustrated) connected to measurement and/or detection means. For example, these means may be arranged to transfer forces exerted by the patient to the weight cell or other measuring means arranged to measure the vertical forces, whereby these means may also be used to measure or indicate non-vertical loads or forces. Hereby, the patient may be able to exert a twisting torque on the leg, e.g. by attempting to turn his foot. The force in e.g. horizontal direction exerted by the foot may then be measured or detected by the measuring means related to the bracket. Further, the patient may exert bending force on the leg by attempting to push the foot forward, backwards or sideways, whereby the force may be measured or detected by the measuring arrangements in a similar manner.

The force exerted by a patient attempting to turn or twist his foot may also be determined by using for example a electromotor, e.g. an electrodynamic motor, arranged axially beneath the support. When the patient attempts to turn his foot, this will have to be done against a torque exerted by the motor. The torque can be determined, as will be obvious to a skilled person, by knowledge of the motor characteristics and by determining the motor current. Further, the maximum torque may be controlled by controlling the motor current, whereby it can be avoided that the patient may place

an excessively large load on the bone, as the motor will just allow further turning when the maximum torque has been reached.

Other safety means may be provided, e.g. audible or visible alarm means which will indicate to the patient and/or to the physician that a certain level of force has been reached which may harm the healing bone. The maximum level or levels of force may be selected and/or adjusted by the physician on the basis of the knowledge of the patient, the state of healing, former tests etc., whereby refractures and other harm to the patient and the healing bone/bones may be avoided. The audible or visible alarm means may also serve to indicate the actual level of force, for example by a frequency increase once the level of force exerted by the patient increases.

Other measuring means obvious to a person skilled in the art may also be utilized.

Another arrangement for measuring the relative flexing movements, e.g. the deformation of a bone, is illustrated in fig. 4. In this figure, only two ring-shaped structural members 22 and 27 of the fixating device are, of course, fixed onto a bone as described in connection with fig. 2 and 3 are described. On one on these ring-shaped members 22 in the example, a camera 41 is placed and points towards the other ring-shaped member 27 in the example. On this ring-shaped member 27, a reference device 42, which must be placed in such a manner that it will be in the vision field of the camera 41 in an unstrained situation of the bone, is placed in a similar manner.

The reference device 42 comprises a number of indicator elements in the form of light emitting diodes (LEDs) 43 for positioning the reference device 42 in the right position in relation to the camera 41. These LEDs 43 are placed in a particular pattern, e.g. in parallel rows and columns as illustrated, in order to facilitate the adjustment and positioning of the reference device 42 and/or the camera 41.

Further, the reference device 42 comprises a number of indicator elements in the form of light emitting diodes (LEDs) 44 for detecting the relative movements, i.e. deformations of the bone. These LEDs 44 are placed opposite a mirror 45 which is

placed at an angle of for example 45° in relation to the plane at which the LEDs 44 are positioned. By this arrangement, deformations of the bone in one, two or three dimensions can be detected and measured. For example, axial deformation can be detected as the distance between the LEDs 44 is known, whereby relative axial movements may be determined by processing the corresponding video images, e.g. the distances on the images. Further, rotational movements can be detected and measured as the initial positions of the reference device 42 and the LEDs 44 are known in the unrestrained situation. The angular movements can be detected and measured as the mirror 45 is involved, whereby the distance on the image between the rows and/or columns of LEDs 44 will change, i.e. the image of the distance between two rows will be larger in one end than in the other end and vice versa, when a tilt between the two ring-shaped members 22 and 27 is involved. Evidently, processing of the measurements from the camera 41 has to be performed in order to achieve values for the deformations of the bone/bones. Such processing may be performed in a number of ways which will be known to person skilled in the art.

Fig. 4 shows only one set of cameras with a reference device by which it will be possible to determine the deformations of a bone. More than one set of cameras and a reference device may be utilized whereby the accuracy of the determined or measured deformations may be improved.

Instead of light emitting diodes, other indicating means may be utilized, for example strongly colored spots, light reflecting means etc. as the purpose is to define reference points detectable to the camera 41.

The mirror 45 may be placed at other angles than the illustrated 45°, whereby corresponding alterations to the configuration may have to be performed, however.

Other means of arranging the light emitting devices may be utilized, for example a number of light emitting devices arranged in two levels in order to provide the necessary information to the camera. Further, additional cameras such as two, three or more, may be provided and correspond to a light emitting device arrangement,

whereby the necessary information concerning the deformation in two or more dimensions may be provided.

Fig. 5 shows a block diagram illustrating an embodiment of the method and apparatus, whereby the deformations of a bone, and in particular a healing bone, can be determined and whereby the strength and/or the state of healing can be determined.

The signals 51a – 51n from a number of sets of measuring arrangements comprising for example video cameras as measurement tools are led to a processing unit 52, wherein the signals are processed in order to determine actual deformations and/or values corresponding to such deformations. When the measuring arrangement is configured as described in connection with fig. 3, at least two measuring arrangements are required while an arrangement as described in connection with fig. 4 may work satisfactorily with only one measuring arrangement.

The processing unit 52 may be connected to a indicating device 53, for example a scale, on which the patient and/or the physician may observe the magnitude of the resulting deformations. Further, the signals 57 from the processing unit 52 are led to a further processing unit 59 which will be described later.

Signals 54a – 54m, for example signals from a weight cell, a force measuring device, a torque measuring device etc., are led to a force signal processing unit 55. This unit may be connected to a force indicator 56, for example in the form of a scale, which allows the patient and/or the physician to observe the force and the load placed on the bone by the patient, for example. Hereby, it may be avoided that an excessive load or force is exerted on the healing bone or bones. The force signal processing unit 55 may process the incoming signals to calculate the actual force which acts on the bone or bones and may indicate this force in normalized and/or standardized values, e.g. the vertical force, horizontal force, force in a forward direction etc. The resulting signals 58 from the force signal processing unit 55 are led to the additional processing unit 59 which serves to correlate the measured and/or detected deforma-

tions with the load or force exerted on the bone or bones. The results 60 hereof may be indicated on a display (not shown), for example in graphical form or as tables, or/and they may be printed. Further, the results may be stored by means of a storing unit 61, whereby the results may be used in connection with testing of the healing state of bones on other patients, on different bones of the same patient, or in connection with subsequent testing of the same bone or bones of the same patient. Further, the test results may be used as e.g. statistical data in connection with improvements of methods for assessing the healing state of bones.

Patent Claims

1. Method of measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and whereby corresponding measurements and/or detections are made of the relative displacement by contactless measurement and/or detection means.

2. Method according to claim 1, characterized in that measurement and/or detection of the relative displacement comprises measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

3. Method according to claim 1 or 2, characterized in that the external fastening means are part of external fixing means for supporting the bone.

4. Method according to claim 1, 2 or 3, characterized in that the bone is subjected to strain, preferably by the patient, and in that the strain is measured, detected and/or visualized.

5. Method according to one or more of claims 1 - 4, characterized in that the corresponding measurements and/or detections of the relative displacement and the strain on the bone are correlated and/or recorded.

6. Method of measuring the strength of a bone, in particular a bone healing after a fracture or an osteotomy, whereby external fastening means are attached onto the bone in at least two locations, whereby said external fastening means are provided with means for detection and/or measurement of relative displacement between said at least two external fastening means, whereby the bone is subjected to strain, and

whereby corresponding measurements and/or detections are made of the relative displacement in at least two dimensions and of the strain on the bone.

7. Method according to claim 6, characterized in that measurement and/or detection of the relative displacement may comprise measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

8. Method according to claim 6 or 7, characterized in that the external fastening means are part of external fixing means for supporting the bone.

9. Method according to claim 6, 7 or 8, characterized in that the bone is subject to strain by the patient and in that the strain is measured, detected and/or visualized.

10. Method according to one or more of claims 6 - 9, characterized in that the corresponding measurements and/or detections of the relative displacement and of the strain on the bone are correlated and/or recorded.

11. Apparatus for measuring the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement by contactless measurement and/or detection means between said at least two external fastening means.

12. Apparatus according to claim 11, characterized in that the apparatus is provided with means for measurement and/or detection of induced strain on the bone.

13. Apparatus according to claim 11 or 12, characterized in that the apparatus is provided with means for correlating said measurements and/or detections of relative displacement of strain.

14. Apparatus according to one or more of claims 11 - 13, characterized in that the means for contactless measurement and/or detection of relative displacement between said at least two external fastening means facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

15. Apparatus according to one or more of claims 11 - 14, characterized in that the external fastening means are part of external fixing means for supporting the bone.

16. Apparatus according to one or more of claims 11 - 15, characterized in that the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring forces to/from the limb to/from measuring means.

17. Apparatus according to one or more of claims 11 - 16, characterized in that the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected strain.

18. Apparatus according to one or more of claims 11 - 17, characterized in that the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected relative displacement.

19. Apparatus for measuring the strength of a bone, in particular a bone having a healing osteotomy or a healing bone fracture, said apparatus comprising external fastening means for connection to the bone in at least two locations, said external fastening means being provided with means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external

fastening means, said apparatus being provided with means for measurement and/or detection of induced strain on the bone.

20. Apparatus according to claim 19, characterized in that the apparatus is provided with means for correlating said measurements and/or detections of relative displacement and strain.

21. Apparatus according to claim 19 or 20, characterized in that the means for detection and/or measurement of relative displacement in at least two dimensions between said at least two external fastening means facilitate measurement and/or detection of a relative longitudinal displacement, a relative rotational displacement and/or a relative angular displacement.

22. Apparatus according to claim 19, 20 or 21, characterized in that the external fastening means are part of external fixing means for supporting the bone.

23. Apparatus according to one or more of claims 19 - 22, characterized in that the apparatus is provided with means for supporting one or both ends of a limb, for positioning one end of a limb and/or for transferring forces to/from the limb to/from measuring means.

24. Apparatus according to one or more of claims 19 - 23, characterized in that the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected strain.

25. Apparatus according to one or more of claims 19 - 24, characterized in that the apparatus comprises means for indicating, visualizing and/or recording the measured and/or detected relative displacement.

26. External fixator for supporting a bone, e.g. a bone in a limb of an animal or a human being, said fixator comprising means for fastening onto the bone in at least two locations and connecting means for providing a preferably adjustable connection

between said fastening means, wherein said connection means are replaceable and wherein measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are attachable onto said at least two external fastening means.

27. External fixator according to claim 26, characterized in that said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are contactless.

28. External fixator according to claim 26 or 27, characterized in that said measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are configured for detection and/or measurement of relative displacement in at least two dimensions.

29. External fixator according to one or more of claims 26 - 28, characterized in that said at least two external fastening means may each comprise or be connected to a structural member which surrounds the body part containing the bone at least partly, and in that said preferably adjustable connection between said fastening means may be connected to said structural members.

30. External fixator according to claim 29, characterized in that said structural members may comprise separate and/or relatively movable parts which may be joined and/or adjusted in order to surround a limb at least partly.

31. External fixator according to one or more of claims 26 - 30, characterized in that the connection means comprise one, two, three, four or more connecting rods, which may preferably be adjustably placed between said at least two fastening means.

32. External fixator according to one or more of claims 26 - 31, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement between said at least two external fastening means are

attachable to said structural members forming part of or being connected to said at least two external fastening means.

33. External fixator according to one or more of claims 26 - 32, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement may be connected to the at least two external fastening means and/or said corresponding structural members by means which also serve as fixing means for said preferably adjustable connection between said fastening means.

34. External fixator according to one or more of claims 26 - 33, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement may comprise electrical, magnetic or electromagnetic measurement and/or detection means.

35. External fixator according to claim 34, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement comprises optical measurement and/or detection means.

36. External fixator according to one or more of claims 26 - 35, characterized in that the contactless measurement and/or detection means for detection and/or measurement of relative displacement comprise one or more measurement and/or detection means.

37. External fixator according to claim 36, characterized in that the measurement and/or detection means for detection and/or measurement of relative displacement in at least two dimensions comprise two or more measurement and/or detection means placed at a circumferential distance, e.g. in relation to an axis of the bone.

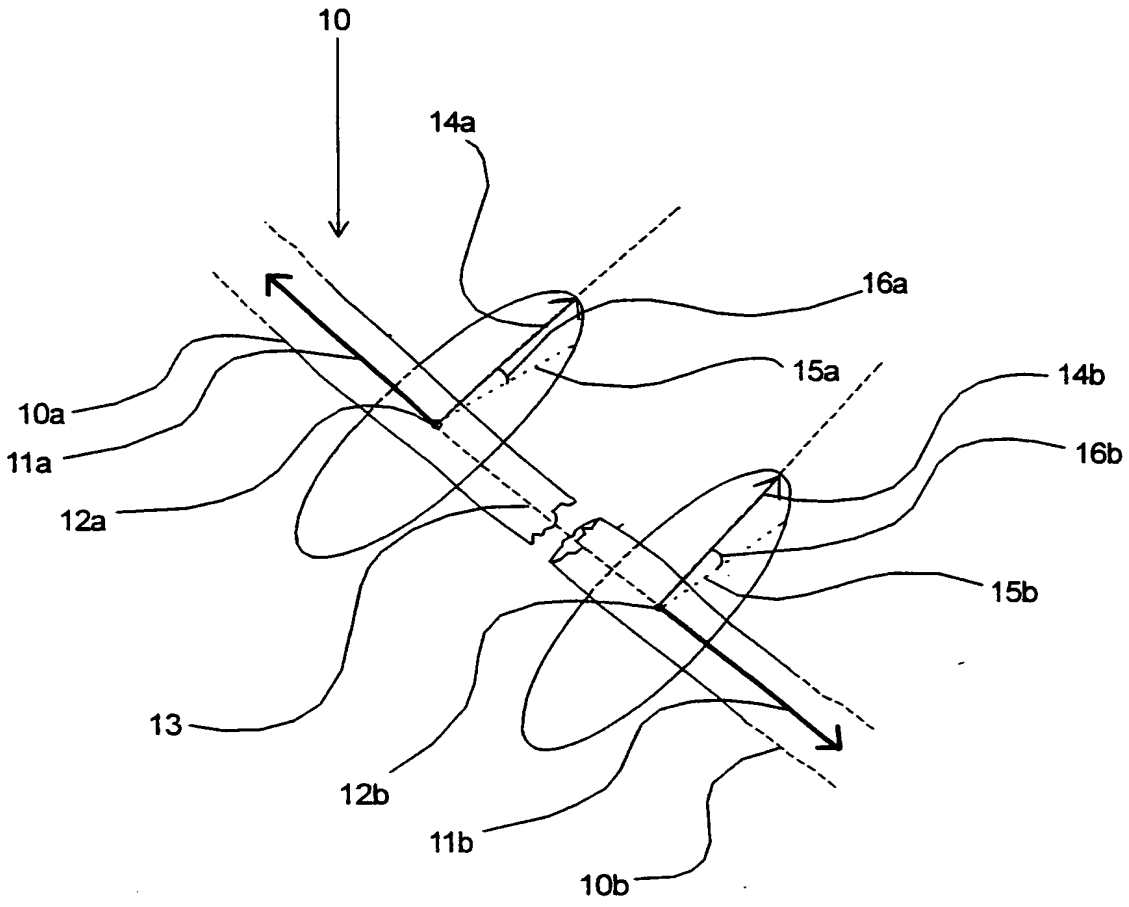

Fig. 1

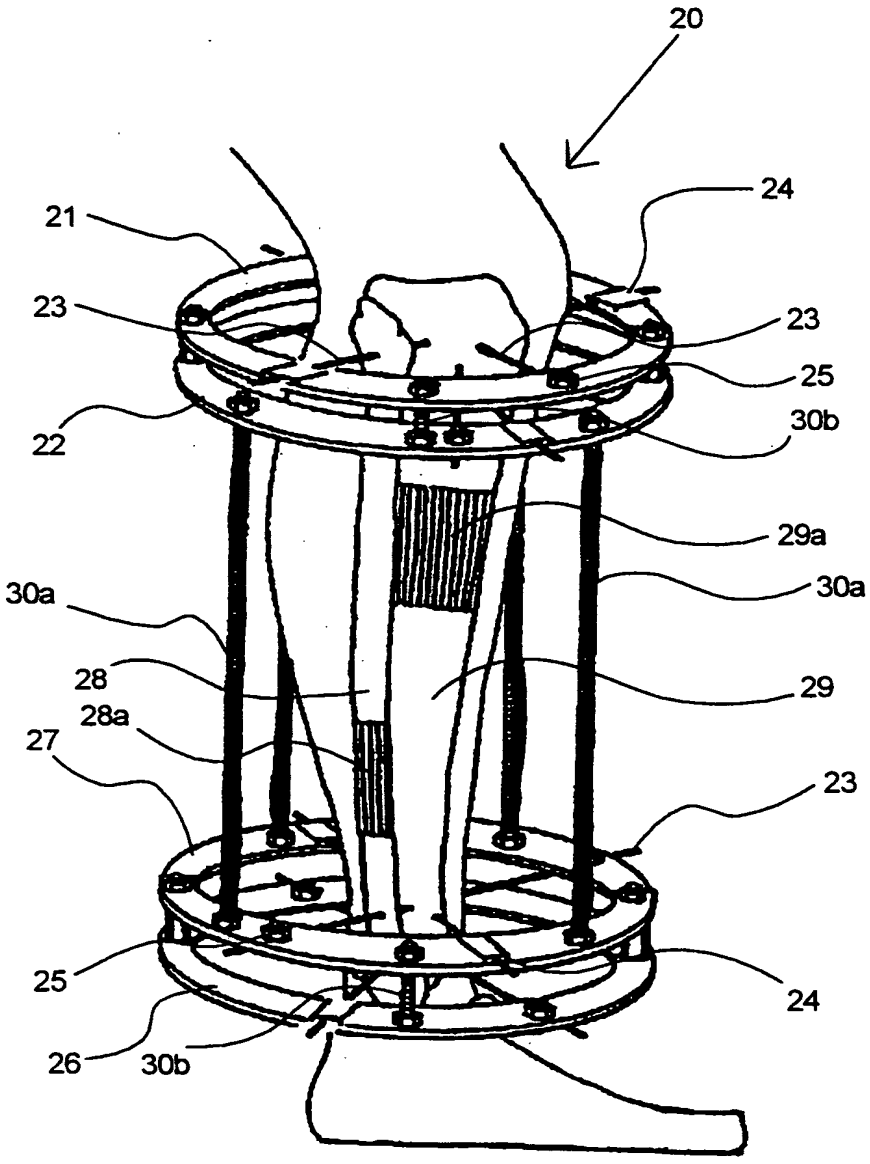

Fig. 2

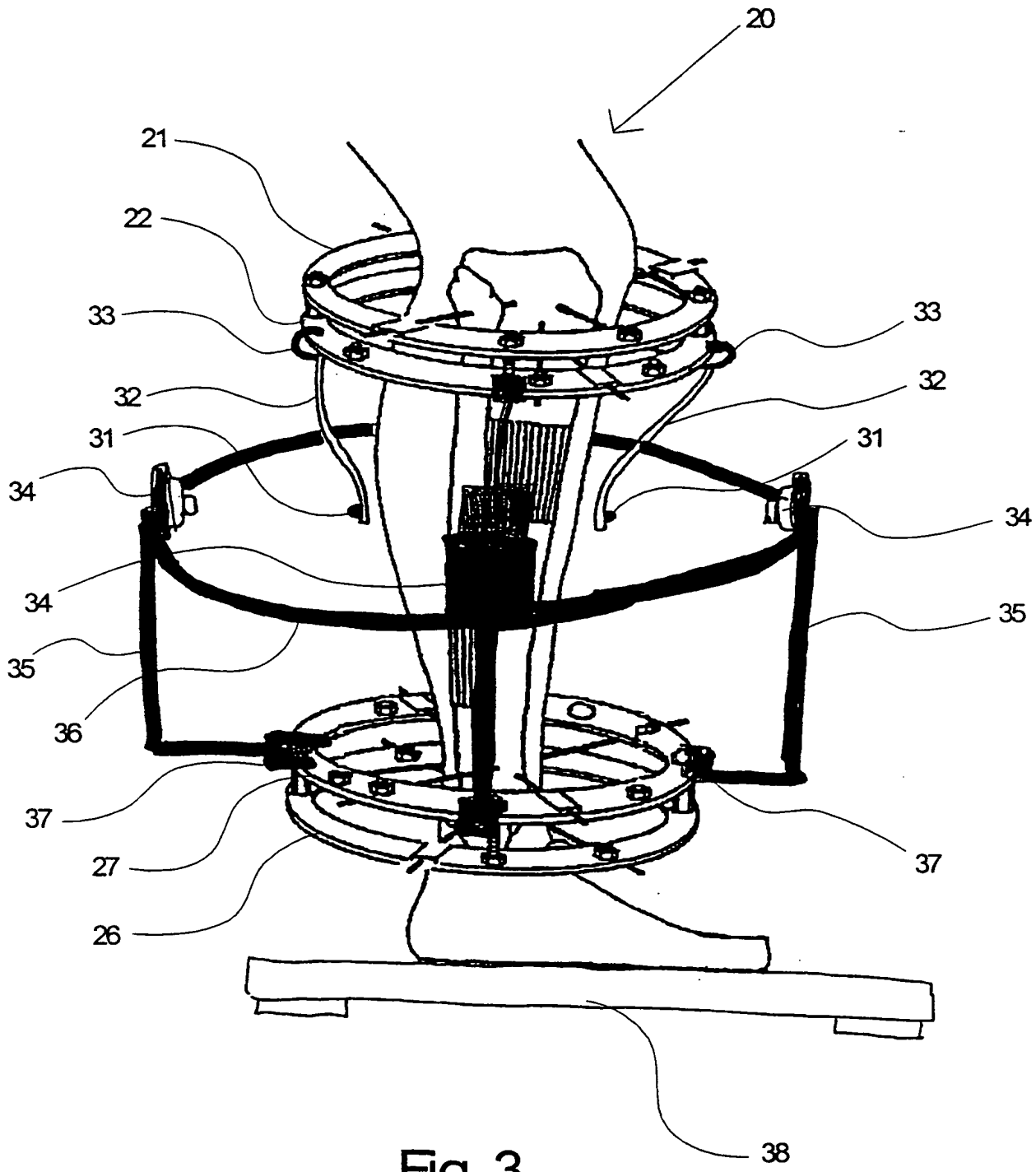

Fig. 3

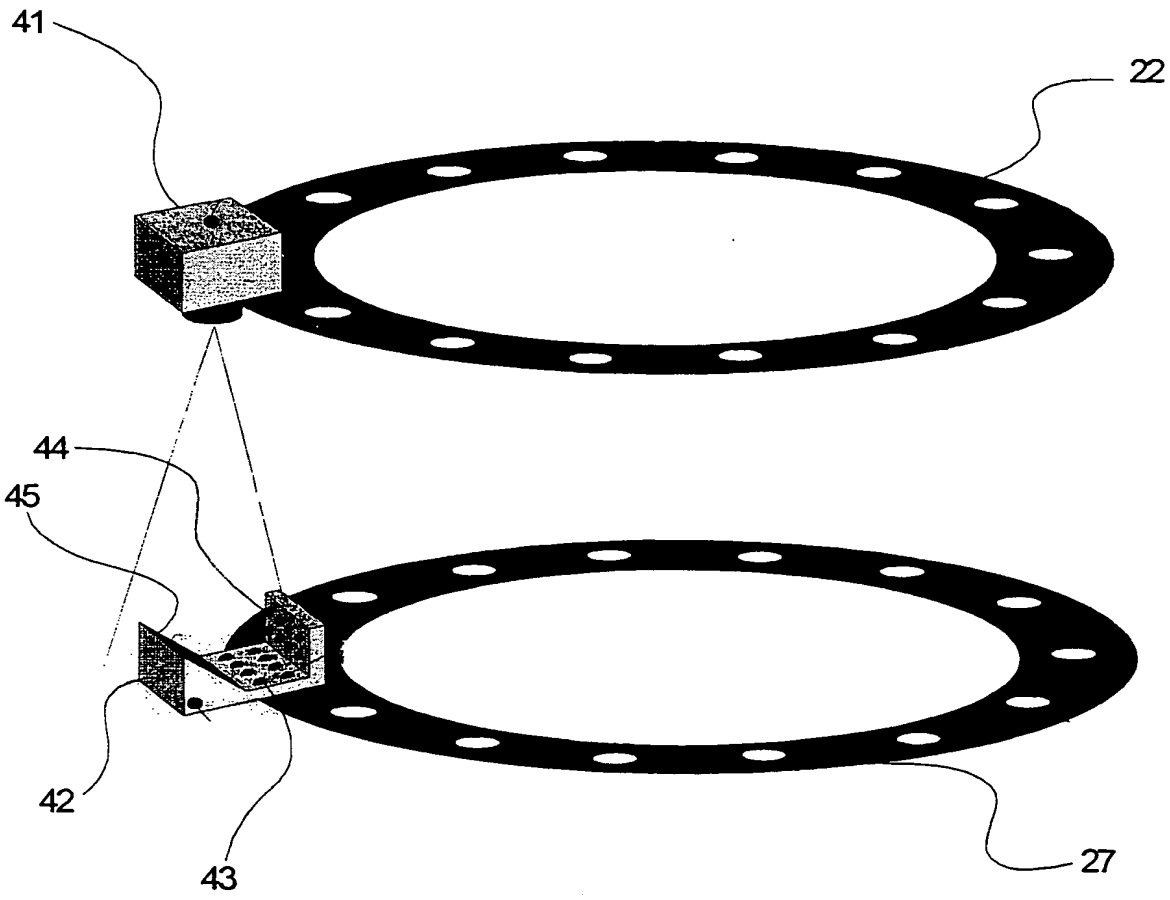

Fig. 4

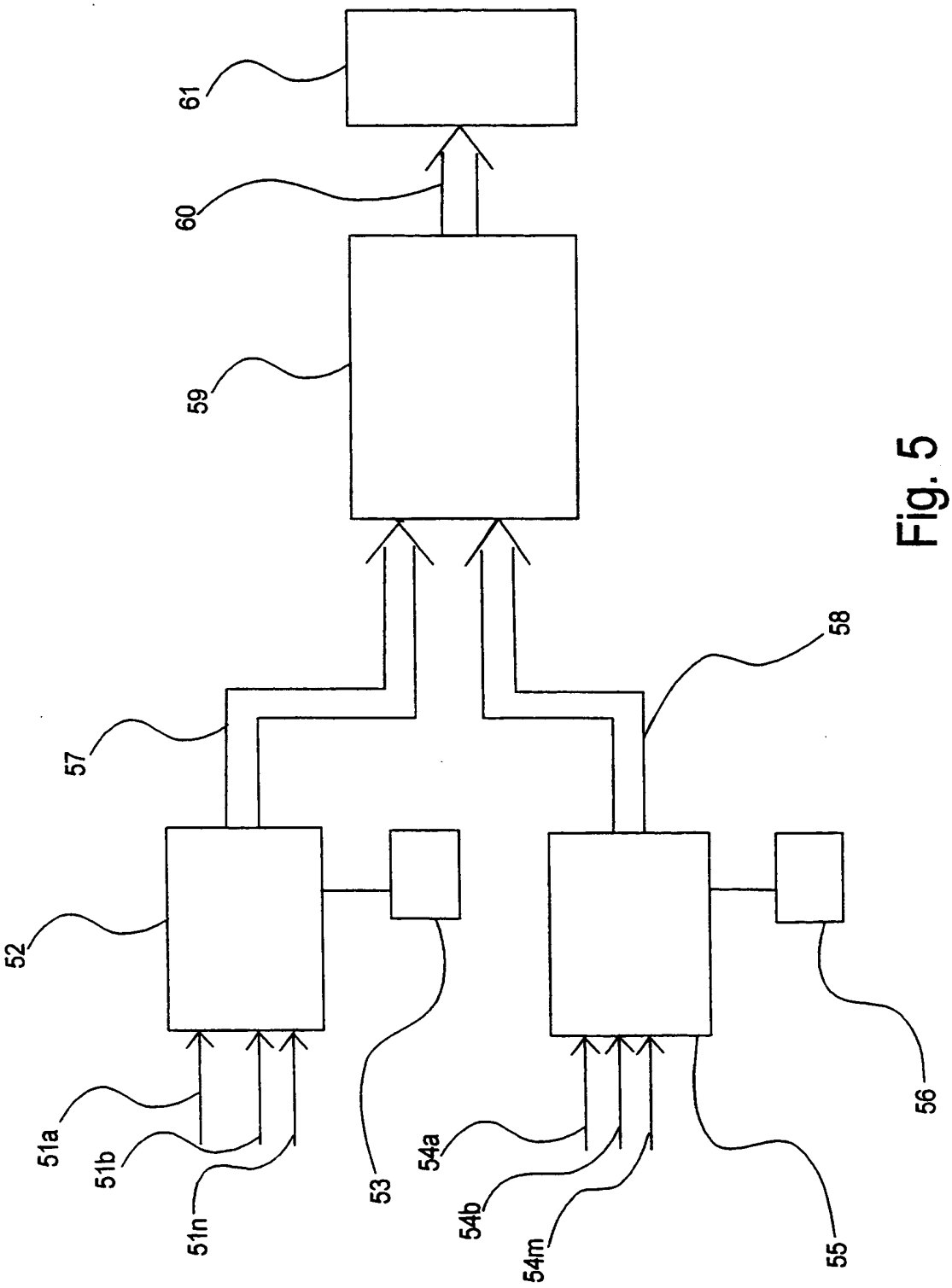

Fig. 5

INTERNATIONAL SEARCH REPORT

International application No.
PC[redacted] 00/00529

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 17/56, A61B 5/103
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0324279 A1 (RICHARDSON ET AL), 29 December 1988 (29.12.88), abstract, fig. ---	1-5,11-18
A	US 4754763 A (DOEMLAND), 5 July 1988 (05.07.88), abstract, fig. --- --------	1-5,11-18

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 January 2001	14 03 2001
Name and mailing address of the ISA: European Patent Office Facsimile No.	Authorized officer Hélène Erikson/JAn Telephone No.

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 00/00529

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0324279 A1	29/12/88	DE 3854386 D,T	14/03/96
		GB 8730257 D	00/00/00
US 4754763 A	05/07/88	EP 0363430 A	18/04/90
		WO 8810090 A	29/12/88

IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *With international search report.*

— *Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

two-dimensional measurement and/or detection means. Hereby, measurements are made which will provide a more accurate assessment of the strength and/or stiffness of a bone. The invention also relates to an external fixator facilitating a method and an apparatus according to the invention.

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 03 July 2001 (03.07.01)	
International application No. PCT/DK00/00529	**Applicant's or agent's file reference** P 00 057 WO
International filing date (day/month/year) 27 September 2000 (27.09.00)	**Priority date** (day/month/year) 28 September 1999 (28.09.99)
Applicant BUNDGÅRD, Kristian, G.	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   10 April 2001 (10.04.01)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer Charlotte ENGER
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
P 00 0577WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/DK 00/ 00529	27/09/2000	28/09/1999
Applicant		
BUNDGÅRD, Kristian, G.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 2 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 3

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/DK 00/00529

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61B 17/56, A61B 5/103
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0324279 A1 (RICHARDSON ET AL), 29 December 1988 (29.12.88), abstract, fig.	1-5,11-18
A	US 4754763 A (DOEMLAND), 5 July 1988 (05.07.88), abstract, fig.	1-5,11-18

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 January 2001	14. 03. 2001
Name and mailing address of the ISA/ European Patent Office Facsimile No.	Authorized officer Hélène Erikson/JAn Telephone No.

SA 307438

INTERNATIONAL SEARCH REPORT

Information on patent family members

27/12/00

[redacted]national application No.
PCT/DK 00/00529

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0324279 A1	29/12/88	DE 3854386 D,T	14/03/96
		GB 8730257 D	00/00/00
US 4754763 A	05/07/88	EP 0363430 A	18/04/90
		WO 8810090 A	29/12/88

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

12

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
P 00 057 WO		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/DK00/00529	27/09/2000	28/09/1999
International Patent Classification (IPC) or national classification and IPC A61B17/56		
Applicant BUNDG RD, Kristian, G.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

I	☒	Basis of the report
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☒	Lack of unity of invention
V	☒	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
VI	☐	Certain documents cited
VII	☒	Certain defects in the international application
VIII	☐	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10/04/2001	28.12.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Weber, P Telephone No. +49 89 2399 2873

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/DK00/00529

I. Basis f th r p rt

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-25 as originally filed

Claims, No.:

1-37 as originally filed

Drawings, sheets:

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-10.

because:

☒ the said international application, or the said claims Nos. 1-10 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

☐ restricted the claims.

☐ paid additional fees.

☐ paid additional fees under protest.

☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

☐ complied with.

☒ not complied with for the following reasons:
see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 11-37.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	11-18
	No:	Claims	19-37
Inventive step (IS)	Yes:	Claims	11-18
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	11-37
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

R It m III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The method of measuring the strength of a bone claimed for in claims 1 to 10, is considered to be part of a diagnosis method so that no examination will be carried out pursuant to Rule 67(1)iv PCT.

Re Item IV

Lack of unity of invention

1. In present set of claims there are three independent claims (four if one includes Claim 1) claiming for three inventions.
It is considered that these three inventions are not so linked as to form a single general inventive concept.

i) Claim 11 (and 1) is directed to an apparatus for measuring the strength of a bone in which contact less detection or measurement means are present between the at least two external fastening means.

ii) Claim 19 is also an apparatus for measuring the strength of a bone comprising means for detection or measurement of relative displacement in at least two dimensions between the at least two external fastening means.

iii) Claim 26 is concerned with an external fixator for supporting a bone and comprising means for fastening onto the bone in at least two locations and connecting means for providing a connection between the fastening means.

Obviously these inventions only have in common very well known elements (external fastening means for connecting to a bone at two locations) which cannot form a general inventive concept.

For this reason the application does not comply with Rule 13 PCT.

R It m V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Claims 11 to 18

1. Apparatuses according to US-A-5339533, EP-A-0324279 or WO-A-98/00062 all comprise external fastening means for connection to the bone in at least two locations and the external fastening means are provided with means for detecting or measurement of relative displacement between the fastening means.

In the apparatus according to Claim 11 the detection or measurement means are means for contact less measurement or detection.

This has the advantage of providing the orthopaedist with values of the strength only depending on the bone itself. No additional support or device enhances the natural strength of the bone so that this leads to a better evaluation of the achieved healing.

Although the means used appear to be relatively simple, none of the cited documents suggests such solution.

For this reasons, Claim 11 fulfils the requirements of Art.33(2)(3) PCT.

2. Claim 12 to 18 being concerned with developments of the invention according to Claim 11, they also fulfil the requirements of Art.33(2)(3) PCT.

Claims 19 to 25

1. Claim 19 requires that the apparatus for measuring the strength of a bone comprises means for detection or measurement of relative displacement in at least two dimensions between the at least two external fastening means.

Such an apparatus is known from D1 : US-A-5339533, see for instance col.8 line 55 to col.9 line 7 or D2 : EP-A-0117859 (cited for the first time), see in particular page 1, page 5 line 2 to line 16. It is to be noted in this context that a rigid bar is also a means

for detecting and/or measuring of relative displacement in a least two dimension as is required by Claim 19.

For these reasons, Claim 19 does not fulfil the requirements of Art.33(2) PCT because its subject-matter appears not to be new.

2. Dependent claims 20 to 25 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty, the additional features of these claims being either known form D1 or D2.

Thus Claims 20 to 25 do not fulfil the requirements of Art.33(2) PCT.

Claims 26 to 37

1. Claim 26 describes nothing else than an external fixator as for example disclosed in D3 : WO-A-98/00062.
In this fixator the connection means are also replaceable by measurement or detection means, the measurement means which are neither precisely defined nor claimed in Claim 26 need only to be adapted to the design of the fastening means.

For this reason Claim 26 does not fulfil the requirements of Art. 33(2) PCT, its subject-matter not being new.

2. Dependent claims 27 to 37 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty all additional features being known from D3.

Thus Claims 27 to 37 do not fulfil the requirements of Art.33(2) PCT

Re Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art

disclosed in the document D3 is not mentioned in the description, nor is this document identified therein.

2. The independent Claims should be presented in the two part form.